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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,348	11/14/2003	Janakiraman Ramachandran	GANG-008	2395

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/715,348		RAMACHANDRAN ET AL.	
	Examiner		Art Unit	
	Robert A. Zeman		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-12-05, 1-24-05, 3-21-05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed on 12-28-2006 is acknowledged. Claim 9 has been amended.

Applicant's election with traverse of Group II in the reply filed on 12-28-2006 is acknowledged. The traversal is on the ground(s) that examination of all the groups can be made without serious burden. This is not found persuasive because the search of the various groups would not be coextensive in scope and thus constitutes a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending. Claims 1-8 and 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 9-15 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statements filed on 1-12-2005, 1-24-2005 and 3-21-2005 have been considered. Initialed copies are attached hereto.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d

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2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10, 13-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4 and 8-9 of U.S. Patent No. 6,913,753. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to methods of inducing a protective immune response against bacterial pathogen utilizing an incapacitated whole cell bacterial vaccine comprising the pathogenic bacteria that has been incapacitated by the expression of a recombinant promoter operably linked to a polynucleotide encoding a gene product. Specifically the bacterial vaccines incapacitated by a Lys negative bacteriophage anticipates the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 9 is rendered vague and indefinite by the use of the phrase “incapacitated whole cell bacterial vaccine”. It is unclear what is meant by the term “incapacitated” with respect to said vaccine. Webster’s dictionary defines the word “incapacitated” as 1) To deprive of strength or ability; 2) To make legally ineligible; disqualify. However, the instant specification has defined “incapacitated” in the context of the claims as meaning that the bacterial cell is in a state of irreversible bacteriostasis. The physical nature of the component of the composition is a critical limitation. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claims 9 and 13 are rendered vague and indefinite by the use of the term the singular term “bacterium”. It is unclear how a single bacterium can have any efficacy as a vaccine.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Majarian et al. (U.S. Patent 6,130,082 – IDS filed 3-21-2005).

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Majarian et al. disclose the use of vaccines comprising bacteria that recombinantly express flagellin fusion proteins (see abstract). Majarian et al. further disclose the use of the T7 promoter system (which includes the T7 polymerase)[see column 15, lines 10-26]. Since the use of the T7 promoter system results in the “hyper expression” of any recombinant protein in a bacterial system leads to them being incapacitated (see page 16 of the specification). Consequently, Majarian et al. anticipates all the limitations of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majarian et al. (U.S. Patent 6,130,082 – IDS filed on 3-21-2005), Kordyum et al. (U.S.

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Patent 6,773,899) and Wright et al. (Science, 1990, Vol. 249 pages 1431-1433 – IDS filed on 1-24-2005).

Majarian et al. disclose the use of vaccines comprising bacteria that recombinantly express flagellin fusion proteins (see abstract). Majarian et al. further disclose the use of the T7 promoter system (which includes the T7 polymerase)[see column 15, lines 10-26). Since the use of the T7 promoter system results in the “hyper expression” of any recombinant protein in a bacterial system leads to them being incapacitated (see page 16 of the specification).

Majarian et al. differ from the instant invention in that they don’t disclose the recombinant expression of a protein that binds LPS generally or LPS binding protein specifically.

Kordyum et al. disclose the use of the T7 promoter system to overexpress biologically active proteins (see abstract).

Wright et al. disclose that LPS binding protein functions as an opsonin as it binds to the surface of bacteria and mediates their adhesion to macrophages.

Consequently, it would have been obvious for one of ordinary skill in the art to express the LPS binding protein disclosed by Wright et al. using the T7 promoter system in the recombinant vaccines of Majarian et al. in order to take care of the increased immunogenicity of the resulting vaccine (due to the opsonin function of the LPS binding protein). One would have had a reasonable expectation of success as Majarian et al. disclose the use of the T7 promoter system and Kordyum et al. disclose that genes

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encoding “any gene of interest” can be used with the T7 promoter system (see column 10, lines 1-2).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Mon - Thur. 7am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Robert Zeman". The signature is fluid and cursive, with the first name "Robert" and last name "Zeman" clearly distinguishable.

ROBERT A. ZEMAN
PRIMARY EXAMINER

April 15, 2007